Clinical Outcomes in Neurogenic Claudication Using a Multimodal Program for Lumbar Spinal Stenosis: A Study of 49 Patients With Prospective Long-term Follow-up

Ngai W. Chow, DC,[a,b,c] Danielle Southerst, DC,[d] Jessica J. Wong, DC, MPH,[c,e] Deborah Kopansky-Giles, DC, MSc,[c,f,g] and Carlo Ammendolia, DC, PhD[h,i,j]

Abstract

Objective: The purpose of this study was to assess long-term outcomes of a 6-week multimodal program (manual therapy, exercises, and self-management strategies) in patients with neurogenic claudication due to degenerative lumbar spinal stenosis.

Methods: This study evaluated 49 patients with neurogenic claudication who completed a 6-week multimodal program between 2010 and 2013. Outcomes included Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and Numeric Rating Scale. Mean differences, paired *t* tests, and the Wilcoxon rank-sum test were used to compare outcomes at baseline, 6 weeks, and long-term follow-up.

Results: Twenty-three patients completed the follow-up questionnaire (47% response rate). Median follow-up was 3.6 years (interquartile range: 3.3-4.6). The mean age was 73.5 years (standard deviation: 8.5). Between baseline and long-term follow-up, there were statistically significant and clinically important improvements in disability (ODI: -23.7 [95% confidence interval (CI): -15.7 to -31.6]; ODI walking item: -1.96 [95% CI: -1.34 to -2.57]; ZCQ function scale: -0.42 [95% CI: -0.10 to -0.70]) and pain (leg pain: -3.53 [95% CI: -1.80 to -5.20]; ZCQ symptom scale: -0.71 [95% CI: -0.30 to -1.10]), but not low back pain (Numeric Rating Scale: -1.03 [95% CI: -1.00 to 3.10]). There was no statistically significant change in any outcomes between 6 weeks and long-term follow-up.

Conclusion: In a sample of patients with neurogenic claudication participating in a 6-week multimodal program, clinically important improvements in leg pain and disability, but not low back pain while walking, were maintained in the long term (median duration of 3.6 years) when compared to baseline. (J Manipulative Physiol Ther 2019;42:203-209)

Key Indexing Terms: *Spinal Stenosis; Lumbar Vertebrae; Osteoarthritis; Spine; Rehabilitation; Chiropractic; Intermittent Claudication; Musculoskeletal Manipulations*

[a] Michael G. DeGroote Institute for Pain Research and Care, McMaster University, Hamilton, Ontario, Canada.
[b] Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, Ontario, Canada.
[c] Graduate Education and Research Programs, Canadian Memorial Chiropractic College (CMCC), Toronto, Ontario, Canada.
[d] Occupational and Industrial Orthopaedic Centre, Langone Orthopaedic Hospital, New York University Langone Health, New York, NY.
[e] University of Ontario Institute of Technology-CMCC Centre for the Study of Disability Prevention and Rehabilitation, Toronto, Ontario, Canada.
[f] Department of Family and Community Medicine, St. Michael's Hospital, Toronto, Ontario, Canada.
[g] Department of Family and Community Medicine, University of Toronto, Toronto, Ontario, Canada.
[h] Rebecca MacDonald Centre for Arthritis & Autoimmune Diseases, Mount Sinai Hospital, Toronto, Ontario, Canada.
[i] Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada.
[j] Department of Surgery, University of Toronto, Toronto, Ontario, Canada.
Corresponding author: Ngai W. Chow, DC, 6100 Leslie Street, Toronto, Ontario, M2H 3J1, Canada. Tel.: +1 416 482 2546. (e-mail: *nchow@cmcc.ca*).

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Introduction

Neurogenic claudication due to degenerative lumbar spinal stenosis (DLSS) is a leading cause of pain, disability, and loss of independence in older adults.[1] It is estimated that more than 200 000 Americans experience DLSS.[2] Due to the aging population, the prevalence and economic burden of this disease is expected to increase exponentially over the next 2 decades.[1,3] Degenerative lumbar spinal stenosis refers to the anatomical narrowing of the central spinal canal, lateral recess, or intervertebral foramen from age-related changes in the lumbar spine (eg, disc bulging, loss of intervertebral disc height, facet joint hypertrophy, osteophyte formation, and ligamentum flavum hypertrophy).[1,4] This can lead to compression and ischemia of the spinal nerves and cause neurogenic claudication. Neurogenic claudication is defined as bilateral or unilateral buttock or lower-extremity pain, heaviness, numbness, tingling, or weakness exacerbated by standing and walking and relieved with sitting and bending forward.[4-6] Limited walking ability is the dominant functional impairment and the most common reason for seeking care in this population.[7] Individuals with neurogenic claudication have greater walking limitations than individuals with knee or hip osteoarthritis[6] and greater functional limitations than those with congestive heart failure, chronic obstructive lung disease, or systemic lupus erythematosis.[1] Inability to walk among individuals with neurogenic claudication leads to a sedentary lifestyle and a progressive decline in health status.[8-10]

Although DLSS is the most common reason for spine surgery in individuals over age 65,[11] only an estimated 21% of patients seeking surgery actually receive surgery.[12] Most patients receive nonsurgical treatment; however, the effectiveness of nonsurgical treatment is unknown.[13-17] Ammendolia et al conducted a 2013 systematic review evaluating the effectiveness of nonsurgical treatments for DLSS and reported that evidence for physical therapy was of low or very-low quality, preventing conclusions to be drawn concerning its effectiveness.[13] Other reviews on this topic have had similar conclusions.[14-16]

One of the authors (C.A.) developed a structured 6-week multimodal training program, known as the *Boot Camp for Lumbar Spinal Stenosis*. This structured multimodal program is tailored and directed to the multifaceted aspects of neurogenic claudication with an emphasis on instructing patients on self-management. A retrospective evaluation of 49 patients with neurogenic claudication demonstrated statistically significant and clinically important improvements in disability and pain after the completion of the 6-week program.[18] The long-term outcomes of this program are unknown. The purpose of this study was to assess the long-term outcomes of the *Boot Camp for Lumbar Spinal Stenosis* in the same group of patients.

Methods

Study Design and Setting

This study was an analysis of 49 patients with long-term follow-up of participants with neurogenic claudication due to DLSS who completed the 6-week *Boot Camp for Lumbar Spinal Stenosis* at a spinal stenosis clinic located at an academic health sciences center in Toronto, Canada, between January 2010 and April 2013.

Ethics Approval

This study received approval from the research ethics boards at Mount Sinai Hospital (REB #15-0006-E) and Canadian Memorial Chiropractic College (REB #1503X03).

Recruitment and Data Collection

The target population was participants who were included in the previous study,[18] age 50 or older with clinical evidence of neurogenic claudication due to DLSS, and completed the *Boot Camp for Lumbar Spinal Stenosis* and questionnaires. Participants were excluded if they had spondylitis, neoplasm, spinal infection, metabolic disease, lumbar disc herniation with radiculopathy, psychiatric or cognitive disorders, or the inability to read or comprehend English. Eligible participants were contacted by phone from September through December 2015 and invited to participate. Long-term follow-up varied from 2 to 5 years, depending on when the participants were initially enrolled in the boot camp program. Questionnaires were distributed via regular mail to those who agreed to participate. Participants completed the questionnaires and returned them via regular mail. Questionnaires were individually coded to allow for comparisons of long-term follow-up responses with those at baseline and 6 weeks. Nonresponders were contacted by 1 author (N.W.C.) via phone for a maximum of 3 attempts.

Description of Boot Camp Program

A full description of the program is available elsewhere.[18] In brief, this structured multimodal program is tailored and directed to the multifaceted aspects of neurogenic claudication with an emphasis on instructing patients on self-management. The program consists of the following: education regarding their condition and instructions on self-management strategies using a cognitive behavioral approach; home-based exercises to improve overall back and lower-extremity fitness and to facilitate lumbar flexion in addition to a graduated walking or stationary cycling program; and manual therapy aimed at reducing pain, improving the flexibility of the lumbar spine, and facilitating lumbar spine intersegmental flexion. All participants completed the program, which consisted of one-on-one treatment sessions with a chiropractor (C.A.). Participants

visited the clinic twice a week for 6 weeks, with each session lasting approximately 15 minutes.

Outcome Measures

Primary Outcome: Oswestry Disability Index (ODI). The ODI is a reliable and valid measure of back-related disability, where 0 represents no disability and 100 represents the worst possible disability.[19] The walking item (ODI walk) of the ODI was scored and recorded separately. The ODI walking item has been shown to be highly correlated (r = 0.83) with the Self-Paced Walking Test, a functional test often used in research to assess objective walking capacity in patients with DLSS.[20] The minimal clinically important difference (MCID) for the ODI ranges from 8% to 12%; for this study, we selected 10% as an indication of a clinically important change in disability.[19]

Secondary Outcomes: Zurich Claudication Questionnaire (ZCQ). Also known as the Swiss Spinal Stenosis Questionnaire, the ZCQ is a validated condition-specific measure consisting of 3 scales: a physical performance scale, a symptom severity scale, and a patient satisfaction scale.[21,22] The physical performance scale consists of 5 questions related to walking ability. The raw scores range from 5 to 20, and a final mean score across all responses is calculated, ranging from 1 to 4. Higher scores reflect lower physical performance. The MCID for the mean scores on the physical performance scale is 0.1.[23] The symptom scale consists of 7 questions pertaining to overall severity of pain, pain frequency, back pain, pain in the leg, numbness, weakness, and balance disturbance. The raw scores range from 7 to 35, and a final mean score across all responses is calculated, ranging from 1 to 5. Higher scores reflect higher symptom severity. The MCID for the symptom severity scale is 0.36.[23]

Low Back Pain and Leg Pain While Walking. These were measured with the 11-point Numeric Rating Scale (NRS), which is a global measure of pain intensity anchored by 2 extremes of pain intensity ranging from 0 (no pain) to 10 (pain as bad as it could be).[24] The MCID for the NRS is 2.[25]

All of the above self-reported outcome measures were collected at baseline, immediately postintervention, and at long-term follow-up.

Data Analysis

Descriptive statistics were recorded for sociodemographic variables, duration of follow-up, and duration of low back and leg pain. Mean differences, 95% CI, and paired *t* tests were used to compare the change in outcomes from baseline to long-term follow-up and from 6 weeks to long-term follow-up. The Wilcoxon rank-sum test was used to compare changes in outcome when data were not normally distributed. The significance level was set at $P < .05$. The proportion of participants who achieved the MCID was also calculated for each outcome measure at long-term follow-up. The SPSS version 24.0 (IBM Corp, Armonk, New York) was used to perform all analyses. To assess for nonresponder bias, baseline demographic data were assessed and compared to responders.

Table 1. *Baseline Characteristics (n = 23)*

Characteristic	Mean (SD)
Age (y)	73.5 (8.5)
Female (%)	65
Duration of follow-up (y)	Median 3.6 (IQR: 3.3-4.6)
Duration of low back pain (y)	13.1 (12.4)
Duration of leg pain (y)	10.6 (12.3)
ODI	32.1 (18.5)
ODI walk	1.96 (1.43)
ZCQ symptom scale	2.72 (0.91)
ZCQ function scale	2.03 (0.85)
NRS low back pain	4.35 (3.10)
NRS leg pain	3.52 (3.46)

IQR, interquartile range; *NRS*, Numeric Rating Scale; *ODI*, Oswestry Disability Index; *SD*, standard deviation; *ZCQ*, Zurich Claudication Questionnaire.

Results

Twenty-three of 49 eligible participants completed the questionnaire (47% response rate). Twelve of the 26 nonresponders originally agreed to participate but were later not reachable, 9 were not reachable due to a change in their phone number or address, 4 were "too tired" or had "no time," and 1 was deceased. Table 1 outlines the baseline characteristics of the included participants. At baseline, 41% of patients reported difficulty walking without an aid compared to 28% and 17% at 6 weeks and at long-term follow-up, respectively. At long-term follow-up, 47.8% of participants reported that they improved a lot or somewhat since completing the program, 52.1% continued to perform the exercises all or most of the time, 39.1% maintained their self-management strategies, and 43.5% received care from other health care providers (eg, orthopedic surgeon, physiatrist, rheumatologist, massage therapist, or physiotherapist).

Change in Outcomes

Between baseline and long-term follow-up (median 3.6 years), there were statistically significant and clinically important improvements in disability (ODI: -23.7 [95% CI: -15.7 to -31.6]; ODI walking item: -1.96 [95% CI: -1.34 to -2.57]; ZCQ function scale: -0.42 [95% CI: -0.10 to -0.70])

Table 2. *Mean Differences in Outcomes From Baseline to Long-term Follow-up*

Outcome	Mean Difference Baseline to 6 Weeks (95% CI)	Mean Difference Baseline to Long-term Follow-up (95% CI)	Mean Difference 6 Weeks to Long-term Follow-up (95% CI)
ODI [a]	-15.2 [b] (-11.39 to -18.92) n = 45	-23.7 [b] (-15.7 to -31.6) n = 22	7.56 (-0.31 to 15.4) n = 21
ODI walk [c]	-0.96 [b] (-0.65 to -1.25) n = 44	-1.96 [b] (-1.34 to -2.57) n = 22	-0.95 (-0.16 to -1.75) n = 21
ZCQ symptom scale [a]	-0.74 [b] (-0.55 to -0.93) n = 44	-0.71 [b] (-0.29 to -1.12) n = 22	0.05 (-0.37 to 0.27) n = 23
ZCQ function scale [a]	-0.41 [b] (-0.26 to -0.56) n = 43	-0.42 [b] (-0.10 to -0.74) n = 22	0.02 (-0.32 to 0.37) n = 23
NRS low back pain [a]	-2.07 (-1.05 to -3.09) n = 29	-1.03 (-1.05 to 3.11) n = 16	0.45 (-1.52 to 2.42) n = 20
NRS leg pain [a]	-2.34 (-1.15 to -3.53) n = 25	-3.53 [b] (-1.83 to -5.23) n = 17	0.90 (-0.94 to 2.74) n = 20

n varied because of missing data.
CI, confidence interval; *NRS*, Numeric Rating Scale; *ODI*, Oswestry Disability Index; *ZCQ*, Zurich Claudication Questionnaire.
[a] Used dependent *t* test.
[b] $P < .05$.
[c] Used Wilcoxon rank-sum test.

and pain (leg pain: -3.53 [95% CI: -1.80 to -5.20]; ZCQ symptom scale: -0.71 [95% CI: -0.30 to -1.10]), but not low back pain (NRS: -1.03 [95% CI: -1.00 to 3.10]). However, between 6 weeks and long-term follow-up, there were no statistically significant or clinically important changes in any of the outcomes for disability (ODI: -7.56 [95% CI: -0.31 to 15.4]; ODI walking item: -0.95 [95% CI: -0.16 to -1.75]; ZCQ function scale [-0.02 (95% CI: -0.32 to 0.37)]) or pain (low back pain while walking: -0.45 [95% CI: -1.52 to 2.42]; leg pain while walking: -0.90 [95% CI: -0.94 to 2.74]; ZCQ symptom scale [-0.05 (95% CI: -0.37 to 0.27)]) (Table 2).

Proportion of Participants Achieving MCID

At 6 weeks, the proportion of participants that achieved MCID was 55% for ODI, 55% for ODI walking item, 63% for ZCQ symptom scale, 59% for ZCQ function scale, 31% for low back pain while walking, and 27% for leg pain while walking (Fig 1). At long-term follow-up, the proportion of participants that achieved MCID was 70% for ODI, 83% for ODI walking item, 52% for ZCQ symptom scale, 61% for ZCQ function scale, 39% for low back pain while walking, and 52% for leg pain while walking (Fig 1).

Characteristics of Responders vs Nonresponders

Table 3 shows the comparison of baseline characteristics of responders vs nonresponders. Responders had a higher mean baseline score on the ODI (55.1 [standard deviation (SD): 11.8] vs 46.5 [SD: 14.9], $P < 0.05$) and a higher mean baseline score on the ODI walking item than nonresponders (3.9 [SD: 1.2] vs 2.9 [1.3], $P < .05$). Furthermore, 52% of responders scored 4 of 5 on the ODI walking item compared with 27% of nonresponders, and 26% of responders scored 5 of 5 compared to 8% of nonresponders. This suggests that responders in this study had a higher mean baseline level of disability than nonresponders.

Discussion

In this study assessing the long-term outcomes of the *Boot Camp for Lumbar Spinal Stenosis*, we observed statistically significant and clinically important improvements in all outcomes (overall symptoms, physical function, disability, leg pain while walking) that were maintained in the long term (median duration of 3.6 years) when compared with baseline, except for low back pain while walking. This is an important finding because in patients with neurogenic claudication due to DLSS, lower-extremity symptoms and limited walking ability, not low back pain intensity, are the dominant functional

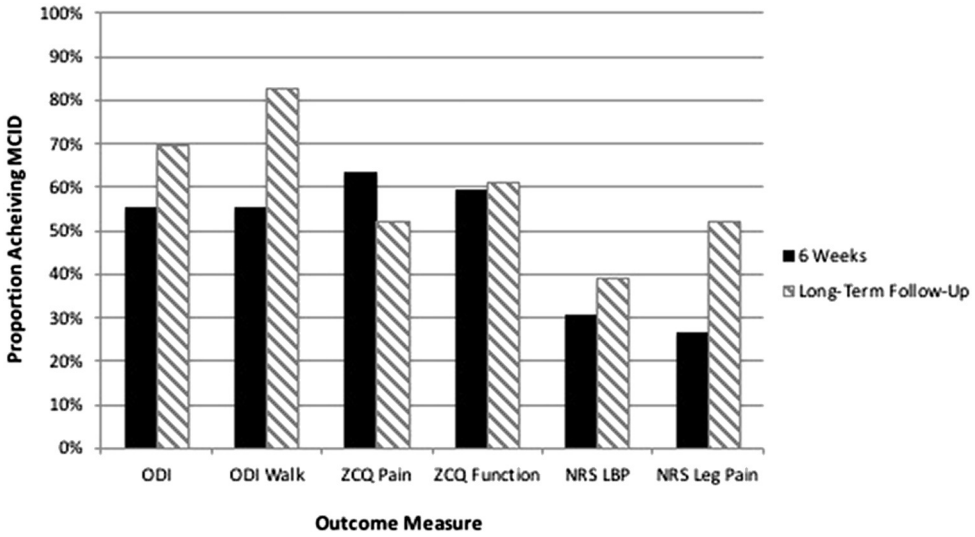

Fig 1. *Proportion of participants who achieved the MCID for each outcome when compared with baseline.* LBP*, low back pain;* MCID*, minimal clinically important difference;* NRS*, Numeric Rating Scale;* ODI*, Oswestry Disability Index;* ZCQ*, Zurich Claudication Questionnaire.*

Table 3. *Comparison of Baseline Characteristics of Responders vs Nonresponders*

	Responders		Nonresponders	
Characteristic	n	Mean (SD)	n	Mean (SD)
Age (y)	23	73.5 (8.5)	26	70.96 (8.6)
Female (%)	23	65	26	65
Duration of LBP (y)	23	10.3 (12.7)	24	11.9 (14.7)
Duration of leg pain (y)	23	9.0 (12.8)	22	8.3 (11.4)
ODI [a]	22	55.1 (11.8) [b]	25	46.5 (14.9) [b]
ODI walk [c]	22	3.9 (1.2) [b]	24	2.9 (1.3) [b]
ZCQ symptom scale [a]	22	3.4 (0.5)	22	3.0 (0.7)
ZCQ function scale [a]	22	2.4 (0.4)	22	2.1 (0.4)
NRS low back pain [a]	16	6.4 (2.7)	21	6.7 (2.4)
NRS leg pain [a]	17	7.3 (1.8)	17	6.8 (2.1)

n varied due to missing data.
NRS, Numeric Rating Scale; *LBP,* low back pain; *ODI*, Oswestry Disability Index; *SD*, standard deviation; *ZCQ*, Zurich Claudication Questionnaire.
[a] Used dependent *t* test.
[b] $P < .05$.
[c] Used Wilcoxon rank-sum test.

impairments and the most common reason for seeking care. Walking ability is best assessed in this population using the Self-Paced Walking Test, and the ODI walking item has been shown to be highly correlated (r = 0.83) with the Self-Paced Walking Test.[20]

The improved outcomes seen in this study are relevant given the increasing prevalence,[6,26] morbidity,[1,8-10,27] and economic burden[3] associated with neurogenic claudication due to DLSS and the lack of evidence for effective nonsurgical treatments.[13-17] However, given that the natural history may be favorable in 33% to 50% of patients,[28] this is a small sample of participants, and the nature of the study design, we cannot conclude that improvement detected in the study population is substantially different than natural history alone. Therefore, further studies using more robust designs and larger samples are necessary. In a systematic review assessing the

effectiveness of nonsurgical treatments for lumbar spinal stenosis, Tran et al (2010) found that all 4 randomized controlled trials (RCTs) of physical therapy plus exercise failed to demonstrate improved long-term outcomes.[14] However, all 4 of those trials were of low methodological quality; therefore, no conclusions could be made about the effectiveness of these interventions.[14] Similar conclusions were reported in other systematic reviews.[13,15] A 2016 systematic review by Zaina et al that compared the effectiveness of surgical vs nonsurgical treatment for DLSS identified 4 trials that included physical therapy.[16] The authors of the 2016 review concluded that there was little confidence to conclude whether surgical treatment or nonsurgical treatment was more effective and that they were unable to provide new recommendations to guide clinical practice.[16] Our findings provide preliminary evidence that the *Boot Camp for Lumbar Spinal Stenosis*, with an emphasis on self-management, can result in clinically important improvements in pain and disability that are sustained in the long term. Future evaluation of the boot camp program is needed using more robust study designs, such as an RCT.

Study Limitations

There were limitations to our study. First, the small sample size may have reduced the power to detect differences in outcomes (type II error). However, we found significant improvement in all but 1 outcome when comparing baseline to long-term follow-up scores. Second, we did not perform any statistical adjustments after conducting multiple *t* tests, which may have led to false positives (type I errors). Third, our response rate was low at 47%, and this may have led to an overestimate of the treatment effects because nonresponders tend to have worse outcomes than responders.[29,30] Furthermore, responders in our study had a higher mean baseline level of disability than nonresponders ($P < .05$), which may have resulted in further overestimation of treatment response. Fourth, our study had no control group or randomization, so it is uncertain whether the improved outcomes observed in our study were superior to "no treatment" (natural history) or "usual care" or compared to other interventions. Therefore, studies with more rigorous study designs are needed to investigate the effectiveness of this program. Finally, no objective measures of walking capacity or performance were used in this study, although the ODI walking item has been shown to be highly correlated (r = 0.83) with the Self-Paced Walking Test.[20]

Future Studies

Two RCTs are currently under way to formally test the effectiveness of the *Boot Camp for Lumbar Spinal Stenosis* and to address the limitations outlined earlier.[31,32]

Conclusion

The results of this study provide preliminary evidence that, in a sample of patients with neurogenic claudication due to DLSS participating in a 6-week multimodal program, clinically important improvements in leg pain and disability, but not low back pain while walking, were maintained in the long term (median duration of 3.6 years) when compared with baseline. However, future studies using more robust study designs are required to confirm these findings.

Funding Sources and Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): N.W.C., C.A.
Design (planned the methods to generate the results): N.W.C., D.S., J.J.W., D.K.-G., C.A.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): N.W.C., D.S., J.J.W., D.K.-G., C.A.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): N.W.C.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): N.W.C., D.S., J.J.W., D.K.-G., C.A.
Literature search (performed the literature search): N.W.C., C.A.
Writing (responsible for writing a substantive part of the manuscript): N.W.C.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): N.W.C., D.S., J.J.W., D.K.-G., C.A.

Practical Applications

- In patients with neurogenic claudication due to DLSS participating in a 6-week multimodal program, clinically important improvements in pain and disability appeared to be maintained over the long term.
- Our findings are relevant given the lack of evidence for the effectiveness (short and long term) of nonsurgical treatments for neurogenic claudication due to DLSSs.
- This information helps generate further hypotheses to explore the effectiveness of this multimodal program in patients with neurogenic claudication due to DLSS using more robust study designs.

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